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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,216	12/04/2001	Keith D. Allen	R-881	6807

7590 10/24/2003

Deltagen, Inc.
740 Bay Road
Redwood City, CA 94063

EXAMINER	
PARAS JR, PETER	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,216	ALLEN, KEITH D.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a targeting construct comprising nucleotide sequences homologous to a TRP6 gene and a method of producing a targeting construct, classified in class 435, subclass 320.1.

II. Claims 3-5, 8 and 15, drawn to cells comprising a disruption in a TRP6 gene, classified in class 435, subclass 325.

III. Claims 6-7, 9, 14, and 16-19 drawn to a transgenic non-human animal, particularly a mouse comprising a disruption in a TRP6 gene, a method of making the same, and a method of using the same to identify an agent that ameliorates a phenotype associated with disruption of a TRP6 gene, classified in classes 800, 800, and 800 subclass 13, 18, and 25.

IV. Claim 10, drawn to a method of identifying agents that modulate the expression or function of a TRP6 gene comprising screening said agents in a transgenic non-human animal, classified in class 800, subclass 3.

V. Claims 11-12, drawn to methods of identifying agents that modulate expression or function of a TRP6 gene in a cell *in vitro*, classified in class 435, subclass 7.2.

VI. Claims 13 and 20, drawn to an unknown agent is unclassifiable.

VII. Claim 20, drawn to an agonist or antagonist or TRP6, classified in class 530, subclass 350.

VIII. Claim 22, drawn to phenotypic data associated with a transgenic mouse comprising a disruption in a TRP6 gene, wherein the data is in an electronic database, classified in class 702, subclass 19.

The products of Inventions I, II, III, VI, VII, and VIII are distinct each from the other. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of Groups I, II, III, VI, VII, and VIII have different chemical structures, are made by different processes, and can be used in different methods which require different technical considerations and materially different reagents. For example, the transgenic animal non-human animal of Group III can be used as a model of disease while the targeting construct of Group I may be used to disrupt a gene in a somatic cell *in vitro*, and the cells of Group II may be used to produce a protein. Also, the unknown agent of group VI has a different chemical structure from the targeting construct, cells, transgenic non-human animals, agonists or antagonists, and phenotypic data of Groups I, II, III, VII, and VIII respectively, and may be used in different methods, which require different technical considerations with respect to modulation of a TRP6 gene. Furthermore, the agonist or antagonist of Group VII appears to have different uses from the products of

Groups I, II, III, VI, and VIII as they may be used to modulate the activity of a TRP6. Finally, the phenotypic data of VIII appears have uses that are unrelated to the products of Groups I, II, III, VI, and VII as such provides a descriptive characterization of the transgenic mouse and can be used for statistical analysis. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between groups IV and V because their methods appear to constitute patentably distinct inventions, each with a distinct purpose and further comprising distinct methodologies and using different products. For example, the method of Group IV requires the use of a transgenic non-human animal to identify agents that modulate expression or function of a TRP6 gene while the method of Group V requires the use of a cell *in vitro* to identify agents that modulate expression or function of a TRP6 gene. Because these inventions are distinct for the reasons given above and a separate search is required for each of Groups IV and V restriction for examination purposes as indicated is proper.

The products of Inventions I, II, III, VI, VII, and VIII and the methods of Inventions IV and V are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects each from the other. The products of Groups I, II, III, VI, VII, and VIII can be used in methods that require different technical considerations and materially different reagents from the methods of Groups IV and V. The methods of Groups IV and V can be practiced with products that have different chemical structures than the products of Groups I, II, III, VI, VII, and VIII. For example, the transgenic non-human animals of Group III may be used to produce antibodies, the cells of Group II may be used to produce a protein, the targeting construct of Group I may be used to disrupt a TRP6 gene in a somatic cell *in vitro*, the agonist/antagonist of Group VII may be used to modulate the function of a TRP6, and the phenotypic data of Group VIII may be used for statistical analysis in an electronic database, while the methods of Groups IV and V may be used to identify agents that modulate the expression of a TRP6 gene. Further, the methods of Groups IV and V may be practiced with agents that have different chemical structures from the agents of Group VI or the agonist/antagonist of Group VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and separate search requirement, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS
PATENT EXAMINER

Bldg/Room

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